

ARCHITEX™ Space Maintenance System

510(k) Summary

December 2010

DEC 13 2010

I. **Company:** **Medtronic Sofamor Danek USA**
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: **Ryan Massey, Sr. Regulatory Affairs Specialist**

- II. **Proposed Proprietary Trade Name:**
ARCHITEX™ Space Maintenance System
- III. **Classification Name(s):** Implants, Endosseous, Root-Form per 21 CFR 872.4760; **Product Code(s):** DZE, JEY
- IV. **Description:**

ARCHITEX™ Space Maintenance System is intended for use in oral-maxillofacial surgical reconstruction and dental regeneration procedures; the implants contained in the System are for maintaining space during bone grating procedures and/or to support soft tissue until bone formation.

The ARCHITEX™ Space Maintenance System consists of a variety of shapes and sizes of screws (Socket Preservation, Tenting, and Mesh Fixation Screws) and titanium mesh implants components as well as placement instruments components. These instruments supplied are general class I instruments added as a convenience for doctors to use to place the provided implants.

The ARCHITEX™ Space Maintenance System includes a selection of Socket Preservation screws which are designed to aid in extraction socket grafting while simultaneously supporting the original gingival margins and papilla.

The ARCHITEX™ Space Maintenance System components are fabricated from medical grade stainless steel and medical grade titanium or titanium alloy. Medical grade titanium and titanium alloy may be used together. The subject implants components will be manufactured from medical grade titanium alloy described by such standards as ASTM F 136-08el or ISO 5832-3, and/or from medical grade unalloyed titanium described by such standard as ASTM F67-06. The placement instruments components will be manufactured from medical grade stainless steel as described in ASTM F8PP-09. The ARCHITEX™ Space Maintenance System is sold non-sterile.

The purpose of this 510(k) application is to seek marketing clearance for the ARCHITEX™ Space Maintenance System to be used as a root-form endosseous dental implants system.

IV. Indications for Use:

The ARCHITEX™ Space Maintenance System is indicated for use as temporary implants to stabilize and support autograft, autograft extenders, allograft, bone void fillers and/or fractured bone segments with or without bone plates or titanium mesh in bony defects of oral maxillofacial anatomy.

The Indications for Use Statement referenced above does not differ from the listed predicate devices.

V. Identification of the Legally Marketed Predicate Devices Use to Claim Substantial Equivalence:

The design features, materials, and indications for use of the ARCHITEX™ Space Maintenance System incorporates a variety of functional aspects from the following predicate devices: TiMesh® System (K062348, SE 09/08/06), ACE Tru-FIX™ Implant System (K080074, SE 02/14/08), and Straumann Dental Implant System (K071585, SE 07/11/07).

| ARCHITEX™ Implant | Predicate | Substantial equivalence |
|----------------------------|---|---|
| Titanium Mesh | TiMesh® (K062348) | Geometrically, materially, and mechanically equivalent |
| Titanium Mesh Screws | TiMesh® (K062348) | Geometrically, materially, and mechanically equivalent. |
| Tenting Screws | ACE Tru-FIX™ (K080074) | Geometrically, materially, and mechanically equivalent. Bone pull-out strength and screw subsidence equivalent to predicate. |
| Socket Preservation Screws | ACE Tru-FIX™ (K080074) | Bone interfacing portion of screw geometrically, materially, and mechanically equivalent. Bone pull-out strength and screw subsidence equivalent to predicate |
| | Straumann Dental Implant System (K071585) | Head portion of screw geometrically, materially, and mechanically equivalent to predicate abutments. |

VI. Brief Discussion of the Non-Clinical Tests Submitted

For a determination of substantial equivalence, the following analysis and bench performance tests were performed on Subject Devices and Predicate Devices:

- Analysis of Dimensional and Material Features
- Statis Axial Pullout Testing in accordance with ASTM F543-02

- Statis Subsidence Testing (To date there is no industry standards)
- Statis Cantilever Bending Testing (To date there is no industry standards)
- Static "Removal Torque" and "Torque to Failure" testing in accordance with ASTM F543-02

VII. Conclusions Drawn from the Non-Clinical Tests

Results of material and dimensional analysis have demonstrated that ARCHITEX™ Space Maintenance System implants are equivalent to the predicate devices in terms of bone/screw interface features.

When compared with predicate devices, results of bench performance testing indicated all acceptance criteria were met, and demonstrated the subject Tenting Screws and Socket Preservation Screws have equivalent static axial pullout and subsidence strength and that the subject Titanium Mesh has equivalent static cantilever bending strength.

The conclusions drawn from the analysis and performance testing, along with the intended use of the subject devices demonstrate that the ARCHITEX™ Space Maintenance System is substantially equivalent to the listed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ms. Michelle Obenauer
Regulatory Affairs Manager
Medtronic Sofamor Danek USA, Incorporated
1800 Pyramid Place
Memphis, Tennessee 38132

DEC 13 2010

Re: K100779

Trade/Device Name: ARCHITEX™ Space Maintenance System
Regulation Number: 21CFR.872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY, DZE
Dated: November 30, 2010
Received: December 1, 2010

Dear Ms. Obenauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICES/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC 13 2010

510(k) Number (if known): K100779

Device Name: ARCHITEX™ Space Maintenance System

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes X OR Over-The-Counter Use No
Per 21 CFR 801.109



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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